

WHAT IS CLAIMED IS:

1. A method of maintaining and/or restoring the viability of at least one organ subjected to a period of ischemia, comprising:

5 perfusing said at least one organ with a first medical fluid at a first temperature to at least one of maintain and restore pre-ischemia ATP and enzyme levels in the organ, wherein the first medical fluid contains oxygen in an amount effective to cause the organ's mitochondria to at least one of maintain and restore pre-ischemia ATP levels in the organ.

10 2. The method of claim 1, wherein the first medical fluid is formulated to avoid injuring the vascular endothelial lining of the organ.

3. The method of claim 1, wherein the first medical fluid is an oxygenated hemoglobin-based solution.

4. The method of claim 1, wherein the first temperature is 12-24°C.

15 5. The method of claim 1, further comprising monitoring the viability of the organ during said perfusing step.

6. The method of claim 5, wherein the viability of the organ is monitored by a sensor that senses fluid characteristics indicative of organ viability and at least one of displays sensed data and relays sensed data to a microprocessor for assessment.

20 7. The method of claim 4, wherein the organ is perfused at least one of intermittently and continuously at the first temperature at a pressure within a range of approximately 40 to 100 mm Hg.

8. The method of claim 1, wherein the organ is perfused at the first temperature utilizing a perfusate pressure source incapable of providing pressures greater than 100 mm Hg.

25 9. The method of claim 1, wherein the organ is perfused at the first temperature with the first medical fluid utilizing a pneumatically pressurized medical fluid reservoir controlled in response to a pressure sensor disposed in tubing inserted into the organ.

30 10. The method of claim 9, further comprising utilizing a stepping motor-activated cam valve controlled in response to the pressure sensor disposed in tubing inserted into the organ to at least one of reduce perfusion pressure and impose a pulse wave on the medical fluid.

11. The method of claim 10, wherein a stepping motor-cam valve is provided for each organ.

12. The method of claim 1, further comprising collecting medical fluid that has passed through the organ in a separate organ bath for each organ, removing  
5 medical fluid from each organ bath, filtering the medical fluid and returning the medical fluid to each organ bath.

13. The method of claim 1, further comprising collecting medical fluid that has passed through the organ from each organ bath and sensing characteristics of the collected medical fluid indicative of organ viability to allow a determination of  
10 whether the viability of the organ has been at least one of sustained and restored.

14. The method of claim 1, further comprising collecting medical fluid that has passed through the organ in each organ bath, filtering, degassing and oxygenating the medical fluid and then either returning the medical fluid to each organ bath or to a medical fluid reservoir based on a sensed pH level of the medical fluid.

15. The method of claim 1, wherein the method further comprises  
15 submerging the organ in a second medical fluid at a second temperature to at least one of store and transport the organ.

16. The method of claim 1, wherein the method further comprises  
20 perfusing the organ with a second medical fluid at a second temperature at least one of intermittently and continuously to at least one of store and transport the organ.

17. The method of claim 16, wherein the second fluid contains substantially no oxygen.

18. The method of claim 17, wherein the second fluid is a simple  
25 crystalloid solution.

19. The method of claim 18, wherein the second fluid contains antioxidants.

20. The method of claim 16, wherein the second temperature is at most  
30 15°C.

21. The method of claim 16, further comprising monitoring the viability of the organ during perfusion at the second temperature.

22. The method of claim 21, wherein the viability of each organ is monitored by a sensor that senses fluid characteristics indicative of organ viability and at least one of displays sensed data and relays sensed data to a microprocessor for assessment.
- 5 23. The method of claim 16, wherein the organ is perfused at the second temperature at a pressure within a range of approximately 5 to 40 mm Hg.
24. The method of claim 16, wherein the organ is perfused at the second temperature utilizing a pressurized medical fluid reservoir configured to provide pressure no greater than 40 mm Hg.
- 10 25. The method of claim 16, wherein the organ is perfused with the second medical fluid at the second temperature utilizing gravity from a pressure head medical fluid reservoir.
26. The method of claim 25, further comprising utilizing a stepping motor-activated cam valve provided for each organ and controlled in response to the pressure sensor disposed in tubing inserted into each organ to at least one of reduce perfusion pressure and put a pulse wave on the medical fluid.
- 15 27. The method of claim 1, wherein the method further comprises perfusing the organ with a second medical fluid at a lower second temperature and subsequently at least one of storing and transporting the organ.
- 20 28. The method of claim 27, further comprising transplanting the organ into a mammal while the organ remains at the second temperature.
29. The method of claim 28, further comprising again perfusing the organ with the first medical fluid at the first temperature after the organ has been transplanted into a mammal.
- 25 30. The method of claim 27, further comprising again perfusing the organ with the first medical fluid at the first temperature prior to transplanting the organ into a mammal.
31. The method of claim 30, further comprising again perfusing the organ with the second fluid at the second temperature prior to transplanting the organ into a mammal.
- 30 32. The method of claim 1, further comprising at least one of storing and transporting the organ in an organ cassette after perfusion of the organ with a second

medical fluid at a second temperature, the organ cassette including a portable housing and an organ supporting surface configured to support an organ while allowing effluent medical fluid to pass therethrough, the portable housing including openings configured to allow tubing to pass therethrough and be connected to the organ.

5           33.    The method of claim 1, further comprising at least one of storing and transporting the organ in an organ cassette after perfusion of the organ with the first medical fluid at the first temperature, the organ cassette including a portable housing; an organ supporting surface; and tubing connectable to the organ to allow perfusion of the organ.

10           34.    The method of claim 1, further comprising prior to perfusing the at least one organ with the first medical fluid at the first temperature, perfusing the organ with a medical fluid containing little or no oxygen.

          35.    The method of claim 34, wherein the medical fluid containing little or no oxygen includes antioxidants.

15           36.    The method of claim 34, wherein the organ is perfused with the medical fluid containing little or no oxygen at a temperature of at least 20°C.

          37.    The method of claim 34, wherein the organ is perfused with the medical fluid containing little or no oxygen at a temperature of at least 15°C.

20           38.    The method of claim 34, wherein the organ is disposed in at least one of a portable container, which is capable of maintaining the organ at a temperature of at most 15°C, and a disposable cassette during perfusion with the medical fluid containing little or no oxygen.

25           39.    The method of claim 1, further comprising prior to perfusing the at least one organ with the first medical fluid at the first temperature, maintaining the organ at a hypothermic temperature.

          40.    The method of claim 1, comprising placing the organ in a portable container, which is capable of maintaining the organ at a temperature of at most 15°C, to at least one of store and transport the organ.

30           41.    The method of claim 1, comprising placing the organ in a portable perfusion unit to at least one of store and transport the organ.

          42.    The method of claim 1, comprising placing the organ in a disposable cassette to at least one of store and transport the organ.

43. The method of claim 1, wherein the organ is disposed in at least one of a portable container, which is capable of maintaining the organ at a temperature of at most 15°C, and a disposable cassette during perfusion of the organ with the first medical fluid at the first temperature.

44. A method of at least one of maintaining and restoring the viability of at least one organ subjected to a period of ischemia, comprising:

perfusing said at least one organ with a first medical fluid at a first temperature to at least one of maintain and restore pre-ischemia energy levels in the organ; and

perfusing the organ with a second medical fluid at a second lower temperature to at least one of store and transport the organ.

45. The method of claim 44, wherein the first medical fluid is an oxygenated solution and the second fluid contains substantially no oxygen.

46. The method of claim 45, wherein the wherein the first medical fluid is an oxygenated hemoglobin-based solution and the second fluid is a simple crystalloid solution augmented with antioxidants.

47. The method of claim 44, wherein the first temperature is 12-24°C and the second temperature is at most 15°C.

48. The method of claim 44, further comprising monitoring the viability of the organ during perfusion of the organ with the first medical fluid at the first temperature and during perfusion of the organ with the second medical fluid at the second temperature.

49. A method of perfusing an organ, comprising:

perfusing said organ utilizing at least one medical fluid reservoir in communication with a pressure source and a fluid pathway connected to the reservoir and connectable to the organ, wherein the reservoir and pathway are configured to perfuse the organ at a perfusion pressure controlled at least in part by varying the pressure provided to the reservoir by the pressure source, wherein the reservoir is a flexible container and the pressure source comprises a cuff disposed around the container.

50. The method of claim 49, wherein the pressure source is incapable of providing a pressure exceeding 100 mm Hg.

51. A method of perfusing an organ, comprising:  
perfusing an organ utilizing at least one medical fluid reservoir, a fluid  
pathway connected to the reservoir and connectable to the organ and a stepper motor-  
activated cam valve disposed on the fluid pathway, wherein the perfusion pressure is  
5 controlled at least in part by the stepper motor-activated cam valve.

52. A method of perfusing an organ, comprising:  
perfusing an organ utilizing at least one medical fluid reservoir in  
communication with a gravity pressure head tank and a fluid pathway connected to  
the pressure head tank and to the organ, wherein the pressure head tank and pathway  
10 are configured to perfuse the organ at a perfusion pressure controlled at least in part  
by the gravity pressure head.

53. A method of perfusing an organ, comprising:  
perfusing an organ with a medical fluid;  
collecting medical fluid that has passed through the organ;  
15 passing the collected medical fluid through a sensor that senses fluid  
characteristics indicative of organ viability; and  
determining whether an organ remains viable based on said sensed fluid  
characteristics.

54. The method of claim 53, wherein the sensed fluid characteristics  
20 include pH, pO<sub>2</sub>, pCO<sub>2</sub>, LDH, T/GST and Tprotein.

55. The method of claim 53, further comprising recording and/or  
transmitting to a location different from the location of the organ said sensed fluid  
characteristics to allow monitoring of the organ's viability.

56. A method of transporting and storing an organ, comprising, in  
25 sequence:

- a. perfusing said organ at a normothermic temperature to repair  
damage from warm ischemia;
- b. perfusing said organ at a hypothermic temperature;
- c. at least one of transporting and storing said organ at a  
30 hypothermic temperature; and
- d. perfusing said organ at a normothermic temperature to repair  
damage from the hypothermic transport or storage of step c.

57. The method of claim 56, wherein said normothermic perfusing steps a and d are performed with an oxygenated perfusion fluid and said hypothermic perfusing step b is performed with a non-oxygenated perfusion fluid.

58. The method of claim 56, wherein step c comprises transporting said organ, and said method further comprises:

e. perfusing said organ at a hypothermic temperature after step d.

59. The method of claim 58, further comprising:

f. storing said organ at a hypothermic temperature after step e.

60. The method of claim 58, further comprising transplanting said organ after step e.

61. The method of claim 56, wherein step c comprises transporting said organ to a storage facility, and said method further comprises:

e. perfusing said organ at a hypothermic temperature and storing said organ at a hypothermic temperature at said storage facility after step d.

62. The method of claim 61, further comprising:

f. perfusing said organ at a normothermic temperature to repair damage from the hypothermic storage of step e;

g. perfusing said organ at a hypothermic temperature; and

h. transporting said organ to a transplant facility at a hypothermic temperature.

63. The method of claim 62, further comprising transplanting said organ after step h.

64. The method of claim 62, further comprising:

f. perfusing said organ at a normothermic temperature to repair damage from the hypothermic transport of step h;

g. perfusing said organ at a hypothermic temperature; and

h. transplanting said organ.

65. Apparatus for perfusing at least one organ, comprising:

at least one flexible medical fluid reservoir;

a pressure cuff disposed around the at least one flexible medical fluid reservoir; and

a fluid pathway connected to the reservoir and connectable to the organ, wherein the organ perfusion pressure is controlled at least in part by varying the pressure provided by the pressure cuff.

5 66. The apparatus of claim 65, wherein the pressure of the pressure cuff is provided by a tank containing compressed gas.

67. The apparatus of claim 65, wherein the pressure of the pressure cuff is provided by a compressor.

68. The apparatus of claim 65, further comprising:  
a pressure sensor disposed in a tip of the fluid pathway connectable to the organ, wherein the pressure cuff is controlled in response to signals from the pressure sensor.

69. The apparatus of claim 65, further comprising a global positioning system for monitoring the location of the organ.

70. Apparatus for perfusing at least one organ, comprising:  
at least one medical fluid reservoir;  
a fluid pathway connected to the reservoir and connectable to the organ; and  
a stepper motor-activated cam valve disposed on the fluid pathway, wherein the organ perfusion pressure is controlled at least in part by the stepper motor-activated cam valve.

20 71. The apparatus of claim 70, further comprising:  
a pressure sensor disposed in a tip of the fluid pathway connectable to the organ, wherein the stepper motor-activated cam valve is controlled in response to signals from the pressure sensor.

72. Apparatus for perfusing at least one organ, comprising:  
at least one medical fluid reservoir;  
a gravity pressure head tank in fluid communication with the at least one medical fluid reservoir; and  
a fluid pathway connected to the pressure head tank and connectable to the organ, wherein the organ perfusion pressure is controlled at least in part by the gravity pressure head.

30 73. Apparatus for perfusing at least one organ, comprising:  
at least one medical fluid reservoir;



a fluid pathway connected to the reservoir and connectable to the organ;  
a first heat exchanger in heat exchange communication with the medical fluid reservoir; and

5 a controller for controlling the first heat exchanger to allow perfusion of the organ with medical fluid at both normothermic and hypothermic temperatures.

74. The apparatus of claim 73, further comprising;  
an organ chamber for holding an organ to be perfused and an organ  
bath of medical fluid that has passed through the organ; and  
a second heat exchanger in heat exchange communication with the  
organ chamber, wherein the controller controls the second heat exchanger to maintain  
the organ bath selectively at both normothermic and hypothermic temperatures.

75. The apparatus of claim 74, wherein the controller is a microprocessor.

76. Apparatus for holding an organ for at least one of perfusion, storage and transport of the organ, comprising:

15 a portable housing;

an organ supporting surface configured to support an organ while allowing effluent medical fluid to pass therethrough, wherein the portable housing is configured to be received by an organ perfusion device and includes openings configured to allow tubing to pass therethrough and be connected to the organ.

20                    77.     The apparatus of claim 76, further comprising a valve supported on an upper portion of the housing and configured to control the pressure of medical fluid passed through tubing operably connected to said valve.

78. The apparatus of claim 77, wherein the valve is a stepper motor-activated cam valve.

25                    79.     The apparatus of claim 76, wherein a bottom portion of the housing is liquid-tight and configured to collect medical fluid that has passed through a perfused organ to form an organ bath.

80. The apparatus of claim 76, further comprising a handle disposed on an outer surface of the portable housing.

30            81.    The apparatus of claim 76, further comprising supports configured to support the apparatus when inserted into an organ perfusion device.

82. Apparatus for holding an organ for at least one of perfusion, storage and transport of the organ, comprising:

- 5 a portable housing;  
an organ supporting surface;  
tubing connectable to the organ to allow perfusion of the organ; and  
at least one connection device configured to allow connection of the tubing to  
tubing of an organ perfusion device.

83. The apparatus of claim 82, further comprising a valve supported on an upper portion of the housing and configured to control the pressure of medical fluid  
10 passed through tubing operably connected to said valve.

84. The apparatus of claim 83, wherein the valve is a stepper motor-activated cam valve.

85. The apparatus of claim 82, further comprising supports adapted to support the apparatus when inserted into an organ perfusion device.

15 86. A perfusion solution kit, comprising a saleable package containing at least one first container holding a first perfusion solution for normothermic perfusion and at least one second container holding a second, different perfusion solution for hypothermic perfusion.

87. The kit of claim 86, wherein said first perfusion solution contains at  
20 least one oxygen carrier.

88. The kit of claim 87, wherein said first perfusion solution is oxygenated and said second perfusion solution is non-oxygenated.

89. The kit of claim 87, wherein said oxygen carrier is selected from the group consisting of a hemoglobin and stabilized red blood cells.

25 90. The kit of claim 87, wherein said oxygen carrier is a hemoglobin.

91. The kit of claim 87, wherein said second perfusion solution contains at least one anti-oxidant.

92. The kit of claim 86, wherein said solution contains no more than 5 mM of dissolved pyruvate salt.

30 93. The kit of claim 87, wherein said second perfusion solution contains at least one vasodilator.

94. The kit of claim 86, wherein said first container and said second container are configured to be operably connected to a perfusion machine as perfusion fluid reservoirs in fluid communication with perfusate conduits of said perfusion machine.

5 95. The kit of claim 94, wherein at least one of said first container and said second container is compressible to apply pressure to the perfusion solution therein.

96. The kit of claim 94, wherein at least one of said first container and said second container includes a first opening for passage of a contained perfusion solution out of said container and a second opening passage of a compressed gas into said container.

10 97. The kit of claim 94, wherein said package is a cassette configured to be operably connected to a perfusion machine for connection of said first container and said second container within said cassette in fluid communication with perfusate conduits of said perfusion machine.

15 98. A control system for controlling perfusion to at least one organ with a medical fluid to maintain viability of the at least one organ, comprising:

an input for inputting organ data;

a perfusion selector for selecting one or more types of perfusion modes;

20 a flow control selector for selecting a type of flow control for each selected perfusion mode;

a controller for controlling flow of the medical fluid based on the selected perfusion mode and flow control;

25 at least one detector for detecting operating conditions experienced by the medical fluid and organ during perfusion;

a comparator for comparing detected operating conditions with prestored operating conditions and generating a signal indicative of organ viability based on the comparison; and

30 an indicator for generating a message relating to organ viability based on the signal generated by the comparator.

99. The control system of claim 98, wherein the flow control selector permits selection between aerobic and anaerobic perfusion for each selected perfusion mode.

5 100. The control system of claim 98, wherein the perfusion selector selects at least one of hypothermic perfusion, normothermic perfusion, and sequential normothermic and hypothermic perfusion.

101. The control system of claim 98, wherein the perfusion selector selects a plurality of medical fluids at different temperatures.

10 102. The control system of claim 98, wherein the perfusion selector selects at least one of intermittent perfusion, single pass perfusion, and recirculation perfusion.

103. The control system of claim 98, wherein the flow control selector selects flow control based on at least one of perfusate flow rate, perfusate pH, organ inlet pressure and timed sequences.

15 104. The control system of claim 98, wherein the at least one detector includes a pressure sensor, a pH detector, and an oxygen sensor.

105. The control system of claim 98, further comprising a thermal controller for controlling temperature of at least one of the perfusate and the organ.

20 106. The control system of claim 105, further comprising an organ container and a perfusate reservoir, wherein the thermal controller regulates temperature of at least one of the organ container and the perfusate reservoir.

107. The control system of claim 105, further comprising a temperature sensor that outputs temperature readings to the thermal controller.

25 108. The control system of claim 98, wherein the perfusion selector and flow control selector include default settings based on organ type.

109. The control system of claim 98, wherein the controller controls perfusion to a plurality of organs.

110. The control system of claim 98, wherein the input accepts data relating to organ type and organ mass.

30 111. A method of controlling perfusion of at least one organ with medical fluid, comprising:

inputting organ data;

selecting one or more types of perfusion modes;  
selecting a type of flow control for each selected perfusion mode;  
controlling flow of the medical fluid based on the selected perfusion  
mode and flow control;

5 detecting operating conditions experienced by the medical fluid and  
organ during perfusion;

comparing detected operating conditions with prestored operating  
conditions and generating a signal indicative of organ viability based on the  
comparison; and

10 generating a message relating to organ viability based on the signal  
generated by the comparator.

112. The method of claim 111, wherein selecting a type of flow control  
includes selecting between aerobic and anaerobic perfusion for each selected  
perfusion mode.

15 113. The method of claim 111, wherein selecting one or more types of  
perfusion modes includes selecting at least one of hypothermic perfusion,  
normothermic perfusion, and sequential normothermic and hypothermic perfusion.

20 114. The method of claim 111, wherein selecting one or more types of  
perfusion modes includes selecting a plurality of medical fluids at different  
temperatures.

115. The method of claim 111, wherein selecting one or more types of  
perfusion modes includes selecting at least one of intermittent perfusion, single pass  
perfusion, and recirculation perfusion.

25 116. The method of claim 111, wherein selecting a type of flow control  
includes selecting flow control based on at least one of perfusate flow rate, perfusate  
pH, organ inlet pressure and timed sequences.

117. The method of claim 111, wherein detecting operating conditions  
includes detecting pressure, pH, and oxygen levels.

30 118. The method of claim 111, further comprising controlling temperature  
of at least one of the perfusate and the organ with a thermal controller.

119. The method of claim 118, wherein controlling the temperature includes  
regulating temperature of at least one of the organ container and a perfusate reservoir.

120. The method of claim 118, further sensing a temperature of at least one of an organ, an organ container, and a perfusate reservoir and outputting temperature readings to the thermal controller.

121. The method of claim 111, further comprising setting default settings based on organ type for use in the steps of selecting perfusion mode and flow control.

122. The method of claim 111, including controlling perfusion to a plurality of organs.

123. The method of claim 111, wherein inputting organ data includes inputting data relating to organ type and organ mass.

124. A recording medium that stores a control program for use by perfusion system that perfuses at least one organ with a medical fluid, the control program including instructions for:

inputting organ data;

selecting one or more types of perfusion modes;

selecting a type of flow control for each selected perfusion mode;

controlling flow of the medical fluid based on the selected perfusion mode and flow control;

detecting operating conditions experienced by the medical fluid and organ during perfusion;

comparing detected operating conditions with prestored operating conditions and generating a signal indicative of organ viability based on the comparison; and

generating a message relating to organ viability based on the signal generated by the comparator.

125. The recording medium of claim 124, wherein selecting a type of flow control includes selecting between aerobic and anaerobic perfusion for each selected perfusion mode.

126. The recording medium of claim 124, wherein selecting one or more types of perfusion modes includes selecting at least one of hypothermic perfusion, normothermic perfusion, and sequential normothermic and hypothermic perfusion.

127. The recording medium of claim 124, wherein selecting one or more types of perfusion modes includes selecting a plurality of medical fluids at different temperatures.

5 128. The recording medium of claim 124, wherein selecting one or more types of perfusion modes includes selecting at least one of intermittent perfusion, single pass perfusion, and recirculation perfusion.

129. The recording medium of claim 124, wherein selecting a type of flow control includes selecting flow control based on at least one of perfusate flow rate, perfusate pH, organ inlet pressure and timed sequences.

10 130. The recording medium of claim 124, wherein detecting operating conditions includes detecting pressure, pH, and oxygen levels.

131. The recording medium of claim 124, further comprising controlling temperature of at least one of the perfusate and the organ with a thermal controller.

15 132. The recording medium of claim 131, wherein controlling the temperature includes regulating temperature of at least one of the organ container and a perfusate reservoir.

133. The recording medium of claim 131, further sensing a temperature of at least one of an organ, an organ container, and a perfusate reservoir and outputting temperature readings to the thermal controller.

20 134. The recording medium of claim 124, further comprising setting default settings based on organ type for use in the steps of selecting perfusion mode and flow control.

135. The recording medium of claim 124, including controlling perfusion to a plurality of organs.

25 136. The recording medium of claim 124, wherein inputting organ data includes inputting data relating to organ type and organ mass.

137. A method of at least one of maintaining and restoring the viability of at least one organ subjected to a period of ischemia or hypoxia, comprising:  
at least one of perfusing and flushing said at least one organ with a first  
30 medical fluid at a first hypothermic temperature to reduce or stop catabolic changes.

138. The method of claim 137, wherein said organ prior to said perfusing step is subjected to said period of ischemia or hypoxia without prior hypothermia.

139. The method of claim 137, wherein said perfusing or flushing step reduces or stops catabolic changes selected from the group consisting of free radical activity, apoptic enzymatic degradation and vascular permeability.

5 140. The method of claim 137, comprising:  
flushing said at least one organ with a first medical fluid; and  
perfusing said at least one organ with a first medical fluid.

141. The method of claim 140, wherein said flushing is performed prior to said perfusing.

10 142. The method of claim 140, wherein said flushing is performed subsequent to said perfusing.

143. The method of claim 137, wherein said first medical fluid comprises at least one member selected from the group consisting of antioxidants, anti-apoptic agents, and agents that decrease vascular permeability.

15 144. The method of claim 137, wherein said organ is continuously perfused with said first medical fluid to ATP recovery over a period of time at said first hypothermic temperature while minimizing catabolic processes initiated by ischemia or hypoxia.

145. The method of claim 137, wherein the first medical fluid is formulated to avoid vascular endothelial damage of the organ.

20 146. The method of claim 137, wherein the first medical fluid comprises at least one marker for viability measurement.

147. The method of claim 137, wherein the first medical fluid comprises an antioxidant that provides effective buffering activity.

148. The method of claim 137, wherein the first temperature is 2-10°C.

25 149. The method of claim 137, wherein the organ is perfused at least intermittently at the first temperature within the range of about 5 to about 60 mmHg.

150. The method of claim 137, wherein the organ is perfused continuously at the first temperature within the range of about 5 to about 60 mmHg.

30 151. The method of claim 137, wherein the organ is perfused at the first temperature using a perfusate pressure source that is incapable of providing pressure greater than 60 mmHg.



152. The method of claim 137, further comprising monitoring the viability of the organ during said perfusing step.

153. The method of claim 152, wherein the viability of the organ is monitored by a sensor that senses fluid characteristics indicative of organ viability and at least one of displays sensed data and relays sensed data to a microprocessor for assessment.

154. The method of claim 152, wherein vascular capillary bed conditions are monitored by a sensor that senses fluid characteristics indicative of vascular capillary bed conditions and at least one of displays sensed data and relays sensed data to a microprocessor for assessment.

155. The method of claim 137, comprising perfusing more than one organ.

156. The method of claim 155, wherein each organ is perfused at the first temperature with the first medical fluid utilizing a pneumatically pressurized medical fluid reservoir controlled in response to a pressure sensor disposed in tubing inserted into each organ.

157. The method of claim 156, wherein each organ is perfused utilizing an individual pneumatically pressurized medical fluid reservoir controlled in response to a pressure sensor disposed in tubing inserted into each organ.

158. The method of claim 137, further comprising collecting medical fluid that has passed through the organ in a separate organ bath for each organ, removing medical fluid from each organ bath, filtering the medical fluid and returning the medical fluid to each organ bath.

159. The method of claim 137, further comprising collecting medical fluid that has passed through the organ from each organ bath and sensing characteristics of the collected medical fluid indicative of organ viability to allow a determination of whether the viability of the organ has been at least one of sustained and restored.

160. The method of claim 137, further comprising collecting medical fluid that has passed through the organ in each organ bath, filtering, degassing and oxygenating the medical fluid and then either returning the medical fluid to each organ bath or to a medical fluid reservoir based on a sensed pH level of the medical fluid.

161. The method of claim 137, wherein the method further comprises switching the perfusion of the organ to a second medical fluid at a second temperature.

162. The method of claim 161, wherein the second medical fluid comprises an oxygen carrier, a free radical scavenger, a pituitary growth factor extract and cell culture media.

163. The method of claim 161, wherein the second medical fluid comprises at least one viability marker.

164. The method of claim 137, wherein the method further comprises perfusing the organ with a second medical fluid at a second temperature at least one of intermittently and continuously to perfuse the organ.

165. The method of claim 164, wherein the second fluid contains an oxygen carrier.

166. The method of claim 165, wherein the second fluid is a simple crystalloid solution carrying dissolved oxygen.

167. The method of claim 166, wherein the second fluid contains at least one of antioxidants and free radical scavengers.

168. The method of claim 164, wherein the second temperature is between about 10 and about 24°C.

169. The method of claim 164, further comprising monitoring the viability of the organ during perfusion at the second temperature.

170. The method of claim 169, wherein the viability of each organ is monitored by a sensor that senses fluid characteristics indicative of at least one of organ viability and vascular capillary bed conditions, and at least one of displays sensed data and relays sensed data to a microprocessor for assessment.

171. The method of claim 164, wherein the organ is perfused at the second temperature at a pressure within a range of approximately 40 to 100 mm Hg.

172. The method of claim 164, wherein the organ is perfused at the second temperature utilizing a pressurized medical fluid reservoir configured to provide pressure no greater than 100 mm Hg.

173. The method of claim 164, wherein the organ is perfused with the second medical fluid at the second temperature utilizing a pneumatic pressure head medical fluid reservoir.

5 174. The method of claim 173, further comprising utilizing pneumatic control or a stepping motor-activated cam valve provided for each organ and controlled in response to the pressure sensor disposed in tubing inserted into each organ to at least one of reduce perfusion pressure and put a pulse wave on the medical fluid.

10 175. The method of claim 137, wherein the method comprises perfusing the organ with the first medical fluid and subsequently at least one of storing and transporting the organ.

176. The method of claim 175, further comprising transplanting the organ into a mammal while the organ remains at the first temperature.

15 177. The method of claim 137, further comprising at least one of storing and transporting the organ in an organ cassette after perfusion of the organ, the organ cassette including a portable housing and an organ supporting surface configured to support an organ while allowing effluent medical fluid to pass therethrough, the portable housing including openings configured to allow tubing to pass therethrough and be connected to the organ.

20 178. The method of claim 137, further comprising at least one of storing and transporting the organ in an organ cassette prior to perfusion of the organ with the first medical fluid at the first temperature, the organ cassette including a portable housing; an organ supporting surface; and tubing connectable to the organ to allow perfusion of the organ.

25 179. The method of claim 137, wherein the organ is perfused with a medical fluid that contains little or no oxygen.

180. The method of claim 179, wherein the medical fluid that contains little or no oxygen comprises at least one member selected from antioxidants, anti-apoptic agents, and agents that decrease vascular permeability.

30 181. The method of claim 179, wherein the organ is perfused with the medical fluid that contains little or no oxygen at a temperature of from about 4 to about 10°C.

182. The method of claim 179, wherein the organ is disposed in at least one of a portable container, which is capable of maintaining the organ at a temperature of at most 10°C, and a disposable cassette during perfusion with the medical fluid that contains little or no oxygen.

5 183. The method of claim 137, further comprising prior to perfusing the at least one organ with the first medical fluid at the first temperature, maintaining the organ at a hypothermic temperature.

184. The method of claim 137, comprising placing the organ in a portable container, which is capable of maintaining the organ at a temperature of at most 10°C, to at least one of store and transport the organ.

185. The method of claim 137, comprising placing the organ in a portable perfusion unit to at least one of store and transport the organ.

186. The method of claim 137, comprising placing the organ in a disposable cassette to at least one of store and transport the organ.

15 187. The method of claim 137, wherein the organ is disposed in at least one of a portable container, which is capable of maintaining the organ at a temperature of at most 10°C, and a disposable cassette during perfusion of the organ with the first medical fluid at the first temperature.

188. A method of at least one of maintaining and restoring the viability of at least one organ subjected to a period of ischemia or hypoxia, comprising:

20 perfusing said at least one organ with a first medical fluid at a first temperature to reduce or stop catabolic changes in the organ; and

perfusing the organ with a second medical fluid at a second temperature to at least one of store and transport the organ.

25 189. The method of claim 188, wherein the first medical fluid is a crystalloid solution and the second fluid contains an oxygen carrier.

190. The method of claim 189, wherein the first medical fluid is a simple crystalloid solution augmented with antioxidants and the second fluid is an oxygenated hemoglobin-based solution.

30 191. The method of claim 188, wherein the first temperature is 4-10°C and the second temperature is at most 10-24°C.

192. The method of claim 188, further comprising monitoring the viability of the organ during perfusion of the organ with the first medical fluid at the first temperature and during perfusion of the organ with the second medical fluid at the second temperature.

5 193. A method of perfusing an organ, comprising:  
perfusing said organ utilizing at least one medical fluid reservoir in communication with a pressure source and a fluid pathway connected to the reservoir and connectable to the organ, wherein the reservoir and pathway are configured to perfuse the organ at a perfusion pressure controlled at least in part by varying the  
10 pressure provided to the reservoir by the pressure source, wherein the reservoir is a flexible container and the pressure source comprises a cuff disposed around the container.

194. The method of claim 193, wherein the pressure source is incapable of providing a pressure exceeding 65 mm Hg.

15 195. A method of perfusing an organ, comprising:  
perfusing an organ utilizing at least one medical fluid reservoir, a fluid pathway connected to the reservoir and connectable to the organ and a variable valve disposed on the fluid pathway, wherein the perfusion pressure is controlled at least in part by the variable valve.

20 196. The method of claim 195, wherein the variable valve is selected from the group consisting of a stepper motor-activated cam valve, a rotary screw valve, and a helical screw valve.

197. A method of perfusing an organ, comprising:  
perfusing an organ utilizing at least one medical fluid reservoir in  
25 communication with a pressure head tank and a fluid pathway connected to the pressure head tank and to the organ, wherein the pressure head tank and pathway are configured to perfuse the organ at a perfusion pressure controlled at least in part by the pressure head.

30 198. A method of perfusing an organ, comprising:  
perfusing an organ with a medical fluid;  
collecting medical fluid that has passed through the organ;

passing the collected medical fluid through a sensor that senses fluid characteristics indicative of organ viability; and

determining whether an organ remains viable based on said sensed fluid characteristics.

5            199. The method of claim 198, wherein the sensed fluid characteristics include pH, pO<sub>2</sub>, pCO<sub>2</sub>, LDH, T/GST, Tprotein and fluorescent tagged copolymer.

200. The method of claim 198, further comprising recording and/or transmitting to a location different from the location of the organ said sensed fluid characteristics to allow monitoring of the organ's viability.

10           201. A method of transporting and storing an organ, comprising, in sequence:

a. perfusing said organ at a mild hypothermic temperature to repair damage from warm ischemia;

15           b. perfusing said organ at a hypothermic temperature, such as a temperature less than said mild hypothermic temperature of said step a;

c. at least one of transporting and storing said organ at a mild hypothermic temperature, such as a temperature greater than said hypothermic temperature of said step b; and

20           d. perfusing said organ at a mild hypothermic temperature to repair damage from the hypothermic transport or storage of step c.

202. The method of claim 201, wherein said mild hypothermic perfusing steps a and d are performed with an oxygenated perfusion fluid and said hypothermic perfusing step b is performed with a non-oxygenated perfusion fluid.

25           203. The method of claim 201, wherein step c comprises transporting said organ, and said method further comprises:

e. perfusing said organ at a hypothermic temperature after step d.

204. The method of claim 203, further comprising:

f. storing said organ at a hypothermic temperature after step e.

30           205. The method of claim 203, further comprising transplanting said organ after step e.

206. The method of claim 201, wherein step c comprises transporting said organ to a storage facility, and said method further comprises:

e. perfusing said organ at a hypothermic temperature and storing said organ at a hypothermic temperature at said storage facility after step d.

207. The method of claim 206, further comprising:

5 f. perfusing said organ at a normothermic temperature to repair damage from the hypothermic storage of step e;  
g. perfusing said organ at a hypothermic temperature; and  
h. transporting said organ to a transplant facility at a hypothermic temperature.

10 208. The method of claim 207, further comprising transplanting said organ after step h.

209. The method of claim 207, further comprising:

15 f. perfusing said organ at a normothermic temperature to repair damage from the hypothermic transport of step h;  
g. perfusing said organ at a hypothermic temperature; and  
h. transplanting said organ.

20 210. Apparatus for perfusing at least one organ, comprising:  
at least one medical fluid reservoir;  
a fluid pathway connected to the reservoir and connectable to the organ;  
a first heat exchanger in heat exchange communication with the medical fluid reservoir; and  
a controller for controlling the first heat exchanger to allow perfusion of the organ with medical fluid at a first hypothermic temperature and a second hypothermic temperature lower than said first hypothermic temperature.

25 211. A perfusion solution kit, comprising a saleable package containing at least one first container holding a first perfusion solution for hypothermic perfusion at a first temperature and at least one second container holding a second, different perfusion solution for hypothermic perfusion at a second temperature lower than said first temperature.

30 212. The kit of claim 211, wherein said first perfusion solution contains at least a crystalloid.

213. The kit of claim 211, wherein said first perfusion solution is crystalloid and said second perfusion solution is oxygen carrier enhanced.

214. The kit of claim 213, wherein said oxygen carrier is selected from the group consisting of a hemoglobin and stabilized red blood cells.

215. The kit of claim 213, wherein said oxygen carrier is a hemoglobin.

216. The kit of claim 211, wherein said second perfusion solution contains at least one anti-oxidant or free radical scavenger.

217. The kit of claim 211, wherein said solution contains no more than 5 mM of dissolved pyruvate salt.

218. The kit of claim 211, wherein said first perfusion solution contains at least one vasodilator.

219. The kit of claim 211, wherein said first container and said second container are configured to be operably connected to a perfusion machine as perfusion fluid reservoirs in fluid communication with perfusate conduits of said perfusion machine.

220. The kit of claim 219, wherein at least one of said first container and said second container is compressible to apply pressure to the perfusion solution therein.

221. The kit of claim 219, wherein at least one of said first container and said second container includes a first opening for passage of a contained perfusion solution out of said container and a second opening passage of a compressed gas into said container.

222. The kit of claim 219, wherein said package is a cassette configured to be operably connected to a perfusion machine for connection of said first container and said second container within said cassette in fluid communication with perfusate conduits of said perfusion machine.

223. A control system for controlling perfusion to at least one organ with a medical fluid to maintain viability of the at least one organ, comprising:

an input for inputting organ data;

a perfusion selector for selecting one or more types of perfusion modes;

a control selector for selecting a type of control for each selected perfusion mode;



a controller for controlling flow of the medical fluid based on the selected perfusion mode and flow control;

at least one detector for detecting operating conditions experienced by the medical fluid and organ during perfusion;

5 a comparator for comparing detected operating conditions with  
prestored operating conditions and generating a signal indicative of organ viability  
based on the comparison; and

an indicator for generating a message relating to organ viability based on the signal generated by the comparator.

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